

Application No.: 09/980,370

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Docket No.: 229752001500

**REMARKS**

Claims 1-11, 18-19 and 21-25 are pending in this application. By this amendment, claims 9 and 11 are amended. No new matter is added by the amendments.

Entry of the amendments and reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience, Applicant's remarks are presented in the same order in which they were raised in the Office Action.

With respect to claim amendments, Applicants have not dedicated to the public or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

**A. Claim amendments**

Claim 9 is amended to depend from claim 1 and specify a nucleotide sequence having at least 90% identity with respect to SEQ ID NO:5, and 90% similarity 90% similarity with respect to SEQ ID NO:6. Support for this limitation is found at page 17, lines 20-22 and elsewhere in the specification. The term "or at least about 20% identity after optimum alignment with same sequence" has been deleted.

Claim 9 part (i) is amended to specify high stringency conditions of "0.1xSSC, and 0.1% w/v SDS at 65 °C." Support for this amendment is found at page 27 of the specification.

Claim 11 is amended to specify "an amino acid sequence having at least 90% similarity to SEQ ID NO:1 or SEQ ID NO:8 after optimal alignment with the same sequence or an amino acid sequence encoded by the nucleotide sequence-SEQ ID NO:7 or a nucleotide sequence having at least 90% identity thereto or a nucleotide sequence capable of hybridizing thereto under high stringency conditions." Support for this limitation is found at pages 17 and 27 of the specification.

No new matter is added by these amendments and entry of the amendments is respectfully requested.

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**B. Claim rejections under 35 U.S.C. § 112, first paragraph**

- (i) Claims 9, 11, 23, 24 and 25 stand rejected as allegedly failing to comply with the written description requirement

The Examiner states that the claims are drawn to a genus of polypeptides that is defined by a functional relationship to SEQ ID NOS: 1, 7 or 8 and insufficient structural characteristics are provided.

In response, Applicants amend claim 9 to specify nucleotides that have "90% identity" to SEQ ID NO:5 or hybridizable at "high" stringency conditions. Claim 9 is further amended to specify a polypeptide having at least 90% similarity to the amino acid sequence of SEQ ID NO:6. Applicants submit that one of skill in the art would find a nucleic acid or amino acid sequence 90% identical to a given sequence or a nucleic acid hybridizable to a given sequence to have sufficient distinguishing identifying characteristics.

Further, claim 9 is amended to depend from claim 1. Claim 1 provides a functional limitation for the claimed HA2 domain. Applicants submit that porphyrin binding by HA2 is a unique interaction which is not replicated by other identifiable receptors. Comparison of the HA2 sequence with other entries in a database of annotated genomic sequence of *Porphyromonas gingivalis* do not identify any HA2 homologs with over 40% similarity and only known HA2 molecules<sup>1</sup> are identified.

Likewise, claim 11 is amended to specify "an amino acid sequence having at least 90% similarity to SEQ ID NO:1 or SEQ ID NO:8 after optimal alignment with the same sequence or an amino acid sequence encoded by the nucleotide sequence SEQ ID NO:7 or a nucleotide sequence having at least 90% identity thereto or a nucleotide sequence capable of hybridizing thereto under high stringency conditions." (emphasis added).

Applicants submit that molecules with nucleotide sequence identity of 90% to a given nucleic acid sequence, or amino acid similarity of 90% to a given amino acid sequence, or nucleic

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<sup>1</sup> The only molecules that were identified by searching the database by the inventors are known HA2 molecules including the high molecular weight lysine-gingipain of *P. gingivalis*, high molecular weight arginine gingipain and Hag2, a putative *P. gingivalis* hemagglutinin.

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acids defined by ability to hybridize under the specified high stringency conditions, provide adequate written description of the claimed sequences. Therefore, Applicants respectfully request withdrawal of this ground for rejection of claim 9 and 11, and claims 23-25 which depend therefrom.

(ii) Claims 1-11, 18-19 and 21-25 stand rejected as allegedly failing to comply with the enablement requirement

The Examiner states that the specification does not provide examples of putative agents which could antagonize interactions between *P. gingivalis* derived molecules having a HA2 domain and the HA2-binding motif on a porphyrin-containing molecule.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. (Genentech Inc. v. NovoNordisk A/S 108 F.3d 1361, 42 U.S.P.Q.2d 1001 (Fed. Cir. 1997)).

The specification, at page 28, line 5 through page 29, line 29 discloses that "porphyrin or porphyrin-like molecules" can be the agent that antagonizes interaction between the HA2 containing molecule and an HA2-binding motif on a porphyrin-containing molecule like hemoglobin.

Specific modified porphyrins that bind HA2 with high affinity but do not support the growth of *P. gingivalis* or do so very poorly, as contemplated by the invention, have been identified by the inventors and reported in Paramaesvaran *et al.*, *J. Bacteriology* 185(8):2528-2537 (Apr. 1003). For example, porphyrin IV (PPIV) binds HA2 with high affinity but does not support growth; deteroporphyrin IX 2,4-bis-ethylene glycol ethylene diamine diamide (DBEG-EDD) inhibits the ability of HA2 to bind hemoglobin, i.e., binds HA2 with high affinity but does not support growth of *P. gingivalis*. (see Paramaesvaran *et al.*, at pages 2532-2535, Figs. 3, 4, 5). A copy of the article is enclosed for the Examiner's convenience.

Accordingly, Applicants submit that the specification teaches one of skill in the art "porphyrin or porphyrin-like molecules" as agents that antagonize interaction between the HA2 containing molecule and an HA2-binding motif on a porphyrin-containing molecule and that such agents taught by the specification could be identified without undue experimentation. Therefore, Applicants respectfully request withdrawal of this ground for rejection.

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In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to *Deposit Account No. 03-1952* referencing docket no. 229752001500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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